K072487

3.0 510(k) SUMMARY

This summary of safety and effectiveness was prepared on 31st August 2007 and is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitted by:

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Title:	Quality Assurance & Regulatory Affairs Manager

FEB 13 2008

Name of Device:

Trade Name:	***FAST1***™ Intraosseous Infusion System
Common Name:	Intraosseous Infusion System
Classification Name:	Hypodermic Single Lumen Needle
Regulation Number:	880.5570
Product Code:	FMI
Class:	Class II
Panel:	80

Predicate Device:

The legally marketed device (predicate device) upon which substantial equivalence to the modified ***FAST1***™ Intraosseous Infusion System is based is:

FAST1™ Intraosseous Infusion System

The 510(k) number for this product is K970380.

Indications for Use:

The ***FAST1***™ Intraosseous Infusion System is indicated for use in establishing a sternal intraosseous access route in adult patients requiring vascular administration of drugs or fluids to facilitate emergency resuscitation.

Description of the Device:

The modified ***FAST1***™ Intraosseous Infusion System is very similar to the ***FAST1***™ Intraosseous Infusion System previously cleared under 510(k) K970380. It consists of a primary component - the infusion tube, and secondary components - the introducer for placing it through the skin into the sternum of the patient, the target/strain-relief patch, protector dome and sharps plug. The minor difference is that the infusion tube of the modified ***FAST1***™ Intraosseous Infusion System can be removed from the patient's sternum by directly pulling on the infusion tubing, whereas the predicate device utilizes a remover tool to remove the infusion tube from the patient's sternum.

Both products are single use, hand-held, manually operated passive devices, (it has no internal energy source). Both products have an infusion tube with a sharp stainless steel tip, a flexible shaft and a standard Luer connector. For both products the user grasps an introducer handle attached to the infusion needle, and pushes the needle tip through the skin and overlying tissue into the sternum of the subject. Fluids or drugs are delivered through the needle to the marrow space of the sternum, and flow out the emissary veins of the sternum into the venous circulation.

Both devices use the same pusher handle and method to insert the infusion needle to the correct penetration depth in the sternum; a mechanism inside the introducer handle disconnects the handle from the infusion needle, preventing the user from pushing the needle any further. The principal of the mechanism is identical for both devices in that it detects the position of the anterior surface of the cortical bone of the sternum, and relates the position of the tip of the infusion needle to the surface of the cortical bone.

Both devices utilize the same adhesive patch which is applied to the top of the patient's chest which the user aligns with the supra-sternal notch of the patient. The position of the recommended insertion site is the same for both devices and is marked on the patch to aid in land marking. Also, the same patch and an associated cover for both devices provide protection and strain-relief to the site and the installed Infusion Tube.

Summary of the Technological Characteristics compared with Predicate Device:

The modified ***FAST1***™ Intraosseous Infusion System and the predicate device are both indicated for use in intraosseous infusion.

The modified ***FAST1***™ Intraosseous Infusion System and its predicate device are similar in that they are passive, hand-held, manually operated devices intended for emergency intraosseous infusion. They both have a handle, at least part of which is removable, which the care-giver uses to place a stainless steel portal tip through overlying tissue into the marrow space of the Manubrium, using only manual force. The Infusion Tubes of both devices have sharp stainless steel tips, a flexible shaft and a standard Luer connector. Both are supplied as biocompatible, sterile, single use products. The revised device does not require a remover tool in order to remove the Infusion Tube. The predicate device does require a remover tool in order to remove the Infusion Tube. Otherwise both devices are similar, and where it is used is identical.

The verification and validation conducted and conclusions demonstrate that the modified ***FAST1***™ Intraosseous Infusion System is as safe and effective as the predicate device K970380.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2008

Dr. Maya Butterfield
Quality Assurance & Regulatory Affairs Manager
PYNG Medical Corporation
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Richmond, B.C., V6V 2E9
CANADA

Re: K072487
Trade/Device Name: FAST1™ Intraosseous Infusion System
Regulation Number: 880.5570
Regulation Name: Hypodermic Single lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: February 5, 2008
Received: February 6, 2008

Dear Dr. Butterfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 INDICATION FOR USE STATEMENT

Indication for Use Statement

510(k) Number (if known):

Device Name: ***FAST1***™ Intraosseous Infusion System

Indications for Use:

The ***FAST1***™ Intraosseous Infusion System is indicated for use in establishing a sternal intraosseous access route in adult patients requiring vascular administration of drugs or fluids to facilitate emergency resuscitation

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073487